

Notice of Allowability	Application No.	Applicant(s)	
	10/531,598	PETTERSSON ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview dated 2/25/10.
2. ☒ The allowed claim(s) is/are 49, 87-92, 94-117.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
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| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>See Continuation Sheet</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2/25/10</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 12/28/09, 12/29/09, 1/4/10, 1/19/10.

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dan Ryan on 2/26/10.

The application has been amended as follows:

Amend claims 49 and 116 as follows:

49 (Currently Amended). A method for treating at least one symptom of gastro-esophageal reflux disease (GERD) in a human suffering from GERD comprising consisting essentially of

(i) identifying a proton pump inhibitor (PPI) selected from a group consisting of lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, and their pharmaceutically acceptable salts, isomers including enantiomers, and pharmaceutically acceptable salts of said isomers,

(ii) identifying an H2 receptor antagonist (H2RA) selected from a group consisting of cimetidine, ranitidine, nizatidine and famotidine, and their pharmaceutically acceptable salts, isomers, and pharmaceutically acceptable salts of said isomers,

(iii) adopting an oral dose regime consisting essentially of:

(a) selecting an oral dosage form for the H2RA for release of H2RA in a gastro-intestinal tract;

(b) selecting an oral dosage form for the PPI for release of PPI in the gastro-intestinal tract and that, when orally administered to the gastro-intestinal tract concurrently with the H2RA, delays and/or extends the release of the PPI relative to the release of the H2RA;

(iv) orally administering the selected oral dosage forms of the PPI and the H2RA concurrently according to the dose regime to affect a rise in gastric pH to above about 3 within

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about 2 hours of administration, thereby treating at least one symptom of GERD promptly, optionally with an antacid agent or an alginate, and

(v) repeating (iv), if necessary over a prolonged period until 6 hours from the administration of the last dose.

wherein the at least one symptom of GERD is selected from a group consisting of heartburn, sour stomach, and upper abdominal pain.

116 (Currently Amended). A method as claimed in claim 49, wherein at least one of the selected oral dosage forms ~~further comprises an~~ contains the antacid agent or ~~in the~~ alginate.

The following is an examiner's statement of reasons for allowance: The closest prior art Goldman et al (5,204,118) does not disclose a method for treating GERD in a patient suffering. The Goldman reference requires the presence of an analgesic in each example while the instant claims exclude an analgesic compound. Further the prior art does not provide a method for treating GERD in a patient suffering from GERD by administering a formulation consisting essentially of a PPI and an H2RA as recited in the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618